UNITED STATES DISTRICT COURT WESTERN DISTRICT OF WISCONSIN

FRANK YOUNG and MICHELLE HAZEN, Individually and as Next Friends for their Minor Son, D.Y.,

Plaintiffs,

v. Case No. 23-CV-235

INJURED PATIENTS AND FAMILIES COMPENSATION FUND, MARSHFIELD CLINIC HEALTH SYSTEM, INC., HOLLY M. FROST, M.D., and CYNTHIA J. HENRY, D.O.,

Defendants.

BRIEF OF DEFENDANT CYNTHIA J. HENRY, D.O. IN SUPPORT OF DAUBERT MOTION/MOTION FOR SUMMARY JUDGMENT

This brief is respectfully submitted by defendant Cynthia J. Henry, D.O. in support of her *Daubert* motion/motion for summary judgment. Although the plaintiffs have disclosed pediatrician Stephen Harris, M.D., and pediatric nephrologist Andrew Stec, M.D., as experts opining on whether the alleged negligence of the defendant physicians was a cause of injury to plaintiff D.Y., their opinions must be struck as not meeting *Daubert* standards such that their cause evidence is purely speculative. Without an expert supporting the plaintiffs' cause element of their medical negligence claim against Dr. Henry, (Doc. 40, ¶¶ 104-107), summary judgment must be granted and the plaintiff's claims dismissed on the merits, with prejudice.

STANDARD OF REVIEW

The admissibility of expert testimony is governed by Fed. R. Evid. 702, as revised in response to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), and amended in 2023¹. In *Daubert*, the Supreme Court interpreted Fed. R. Evid. 702 to require the district court to act as an evidentiary gatekeeper, ensuring that an expert's testimony rests on a reliable foundation and is relevant. *Daubert*, 509 U.S. at 597. This is because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it." *Id.*, 509 U.S. at 595 (citation omitted).

In performing its gatekeeper role, the district court must engage in a multi-step analysis before admitting expert testimony.

First, the expert must be qualified by knowledge, skill, experience, training, or education; second, the proposed expert testimony must assist the trier of fact in determining a relevant fact at issue in the case; third, the expert's testimony must be based on sufficient facts or data and reliable principles and methods; and fourth, the expert must have reliably applied the principles and methods to the facts of the case.

Lees v. Carthage College, 714 F.3d 516, 521-522 (7th Cir. 2013)(emphasis added). It is this third step that is at issue in this motion. "Federal Rule of Evidence 702 allows an expert

Although the amendments to Rule 702 that took effect on December 1, 2023 do not impose any new, specific procedures, they clarify that the proponent of expert testimony must meet Rule 702's substantive standards for admissibility by a preponderance of the evidence. "[M]any courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a)." Fed. R. Evid. 702 Advisory Committee Notes to 2023 Amendments.

witness to testify about a relevant scientific issue in contention if his testimony is based on sufficient data and is the product of a reliable methodology correctly applied to the facts of the case." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010).

In assessing the reliability of an expert's testimony, a court should consider the methodology used to arrive at a particular conclusion. *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). "Rule 702 imposes 'a special obligation upon a trial judge to "ensure that any and all scientific testimony . . . is not only relevant, but <u>reliable</u>."" *Clark v. Takata Corp.*, 192 F.3d 750, 758 (7th Cir. 1999)(citation omitted)(emphasis added). Before admitting expert testimony, the court should be assured "the expert knows whereof he speaks." *Bammerlin v. Navistar International Transportation Corp.*, 30 F.3d 898, 901 (7th Cir. 1994).

The objective of [*Daubert*'s gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

Kumho Tire, at 152. Ultimately, the expert's opinion "must be reasoned and founded on data. It must also utilize the methods of the relevant discipline [. . . .]" *Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 894 (7th Cir. 2011).

In addition, the summary judgment standard of review establishes the Court shall grant summary judgment if the movant shows there "is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). One

of the principal purposes of the rule is to dispose of factually unsupported claims. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-324 (1986). The moving party is entitled to judgment as a matter of law if the non-movant fails to make a sufficient showing of an element of its case with respect to which it has the burden of proof, which here is causation. *Id.* at 325.

ARGUMENT

I. The plaintiffs' state law medical negligence claim requires an expert to establish causation.

Wisconsin law governs the plaintiffs' substantive claims, as acknowledged by the plaintiffs in their second amended complaint (Doc. 40, ¶ 105), and defines the burden of proof the plaintiffs must present to establish the elements of each claim. *See C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015). To succeed on a claim of medical malpractice, a plaintiff must prove a negligent act or omission that is below the standard of care caused an injury. *Paul v. Skemp*, 2001 WI 42, ¶ 17, 242 Wis. 2d 507, 625 N.W.2d 860. "To establish causation in Wisconsin, the plaintiff bears the burden of proving that the defendant's negligence was a substantial factor in causing the plaintiff's harm." *Ehlinger by Ehlinger v. Sipes*, 155 Wis. 2d 1, 12, 454 N.W.2d 754 (1990). Expert testimony is required to prove causation where, as here, "the matter is not within the realm of ordinary experience and lay comprehension." *Pinter v. Vill. of Stetsonville*, 2019 WI 74, ¶ 63, 387 Wis. 2d 475, 929 N.W.2d 547 (citation omitted).

Whether Dr. Henry was causally negligent in her care and treatment of D.Y. is not within the realm of jurors' ordinary experience and lay comprehension, and therefore an

expert is required to establish causation. Failure to secure expert testimony to establish liability, causation, and damages is grounds for a motion for summary judgment. *Kasbaum v. Lucia*, 127 Wis. 2d 15, 21-24, 377 N.W.2d 183 (Ct. App. 1985). When expert testimony is required, and no expert is presented, the evidence is insufficient to support a claim. *Kinnick v. Schierl, Inc.*, 197 Wis. 2d 855, 862, 541 N.W.2d 803 (Ct. App. 1995). "[T]he lack of expert testimony on the question of causation results in an insufficiency of proof where the issue involves technical, scientific or medical matters which are beyond the common knowledge or experience of jurors and the jury could only speculate as to what inference to draw." *Ollman v. Wisconsin Health Care Liab. Ins. Plan*, 178 Wis. 2d 648, 667, 505 N.W.2d 399 (Ct. App. 1993)(citation omitted).

II. Pursuant to *Daubert*, the testimony of Dr. Stec and Dr. Harris is inadmissible to establish causation.

A. Background of the underlying issue presented in this motion.

D.Y. was noted to have mild bilateral pyelocaliectasis on his second day of life, March 28, 2014, pursuant to an ultrasound study performed at St. Joseph's Hospital in Marshfield, Wisconsin. (PFOF, ¶4). Dr. Henry saw D.Y. from April 3, 2014 until July 14, 2015 for well child checks, as did Dr. Gary Pusateri and other providers at the Lac Vieux Desert Health Center. (PFOF, ¶¶ 5 and 6). Whether Dr. Henry attempted to address D.Y.'s urinary issue with his parents is a matter of dispute.

It is undisputed, however, that D.Y. did not evidence any urinary dysfunction or symptoms until February 20, 2018. (PFOF, ¶ 7). He was diagnosed with bilateral

hydronephrosis and a trabeculated bladder by pediatric urologist Charles Durkee, M.D. on April 23, 2018. (PFOF, ¶ 8). On May 7, 2018, Dr. Durkee found that D.Y.'s urethra (the passage from the bladder to the end of the penis) had a "surprisingly [] large polyp of the verumontanum which appeared like it could readily ball valve down into the external sphincter." (PFOF, ¶ 9). Dr. Durkee removed the polyp, which was found to be a benign epithelial growth. (PFOF, ¶ 10). Since its removal, and with additional treatment, D.Y.'s hydronephrosis has essentially resolved and his bladder function has improved so that currently he is able to urinate in a normal anatomic manner. (PFOF, ¶ 11).

B. The opinions of Dr. Stec do not meet the *Daubert* reliability requirement.

Dr. Stec was retained by the plaintiffs to opine on the issue of causation. (PFOF, ¶ 12).

Dr. Stec provided what he denominated as 12 opinions in this case. (PFOF, ¶¶ 13 and 14).

He concluded that D.Y.

[d]id not have appropriate follow-up for his prenatally diagnosed hydronephrosis. The diagnosis of bladder outlet obstruction due to urethral polyp was not diagnosed until four years of age when urinary symptoms began, and end organ damage had already occurred to the kidney and the bladder. Had recommended follow-up been performed for the prenatal hydronephrosis, progressively worsening hydronephrosis would more likely than not been discovered. This would have prompted earlier referral to a pediatric urologist and a more prompt VCUG [voiding cystourethrogram]. The bladder outlet obstruction would have been uncovered and the polyp removed sooner. Minimal to no injury of the kidneys and bladder would have likely occurred. Due to the delay in diagnosis, permanent kidney and bladder impairment occurred to D. Y. That will result in lifelong medical issues.

(PFOF, ¶ 13, p. 8). Dr. Stec issued a supplemental report dated May 12, 2024. (PFOF, ¶ 14).

That report did not change any of his prior opinions. *Id.*, p. 2.

Dr. Stec was subsequently deposed. (PFOF, ¶ 15). Dr. Stec conceded:

- The vast majority of hydronephrosis that is seen in pediatric patients is in the mild category. (PFOF, ¶ 16).
- A finding of hydronephrosis in a pediatric patient is a common finding.
 - Q: But my understanding is, as you said, this is one of the most common findings that you see, urological findings that you see in pediatric in pediatric patients, correct?
 - A: Yes.

(PFOF, \P 17).

- As noted by Dr. Stec, "[t]he vast majority of them [mild hydronephrosis cases] don't require treatment." (PFOF, ¶ 18).
- Mild hydronephrosis cases do not require treatment.
 - Q: But so they [mild hydronephrosis cases] may persist in a mild fashion, but don't require treatment?
 - A: Yes.

Id.

Even more significant, Dr. Stec admitted:

- He has never treated a patient with a urethral polyp. (PFOF, ¶ 20).
- He is not aware of anyone at the institutions at which he has practiced having cared for a pediatric patient with a urethral polyp. (PFOF, \P 21).
- He had not done any research regarding urethral polyps developing in pediatric patients. (PFOF, ¶¶ 19 and 22).

- He was unaware of any case studies involving urethral polyps. (PFOF, ¶ 23).
- He was unaware when urethral polyps start to develop. *Id.*
- He was unaware how fast urethral polyps can develop, (PFOF, ¶¶ 23 and 28), and he was unaware of the ages of patients seen with urethral polyps. (PFOF, ¶ 32).
- He is not familiar with any articles or medical literature that address urethral polyps. (PFOF, ¶¶ 24 and 26).

Of primary importance, Dr. Stec admitted he was not relying on any scientific research for his testimony, (PFOF, \P 27), and could not identify any literature to support his opinion that the tissue that later developed into the polyp found in 2018 was actually causing the mild hydronephrosis at the time of birth in 2014. (PFOF, \P 29).

Overall, Dr. Stec has not had any experience in treating a urethral polyp.

- Q: We are dealing with a very unique rare incident of a polyp developing in the verumontanum, something you've never seen and you are unaware of anyone who has had to address that medically, true?
- A: I am. I am not aware. But what I have seen are boys with bilateral hydronephrosis they get progressive over time where we diagnose them with bladder outlet obstruction. So that is something that is rare to me. From a polyp, yes, But the disease process, no.
- Q: But you have no idea because you've never seen it and experienced it when a polyp in the verumonatnum how rapidly that may grow and how obstructive it may occur, it may be in a matter of months?
- A: Specifically to a polyp, no, I don't have any way to characterize how fast a polyp grows, I don't know that.

(PFOF, ¶ 30)(emphasis added).

The testimony of Dr. Stec establishes he does not have any direct or indirect experience with urethral polyps developing in a pediatric patient, and cannot provide any peer-reviewed medical literature or studies to support his opinion that a urethral polyp was a cause of mild hydronephrosis in 2014, or a urethral polyp was present and detectable during Dr. Henry's care of D.Y. *Daubert* applies "where an expert eschews reliance on any rigorous methodology and instead purports to base his opinion on 'experience' or 'training." Clark, at 758 (citation omitted). "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." Gen Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). "Proposed testimony must be supported by appropriate validation -i.e., 'good grounds,' based on what is known." *Daubert*, at 590. "The expert's testimony must be grounded in an accepted body of learning or experience in the expert's field, and the expert must explain how the conclusion is so grounded." Fed. R. Evid. 702, Advisory Committee's Notes (2000 Amendment). "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Id.*

"The question [the court] must ask is not whether an expert witness is qualified in general, but whether his 'qualifications provide a foundation for [him] to answer a specific question." *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010)(citation omitted). The party seeking to offer an expert's testimony bears the burden of establishing its admissibility under

Daubert by a preponderance of the evidence. *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 782 (7th Cir. 2017).

In the present case, Dr. Stec does not possess the requisite knowledge, skill, experience, training, or education to provide expert testimony as to causation where the obstruction found at age four was a urethral polyp. In other words, Dr. Stec lacks qualifications to provide a foundation for him to answer the question as to whether the alleged negligence of Dr. Henry was a cause of D.Y.'s injuries. Dr. Stec lacks any relevant experience qualifying him to opine about the growth of a urethral polyp. Dr. Stec conceded he had no direct or indirect experience with urethral polyps developing in a pediatric patient. Moreover, Dr. Stec could not provide any medical literature or studies to support his opinions that a urethral polyp was a substantial factor in causing the mild hydronephrosis or that a urethral polyp developed slowly so that it would have been present or detectable during Dr. Henry's care and treatment of D.Y. Conversely, a urethral polyp is virtually unknown in medical science. Medical science demonstrates the changes seen in D.Y.'s bladder can develop in 12 months or even less, analogous to other urinary tract obstructions. In fact since removal of the urethral polyp, D.Y. has near normal kidney function, and hydronephrosis has essentially resolved.

Dr. Stec also admitted he has never treated a pediatric patient who developed a urethral polyp. In fact, Dr. Stec was unaware of anyone with that condition *prior to this case*. He also conceded not doing any research on the prevalence of urethral polyps, and acknowledged it is an exceedingly rare condition. (PFOF, ¶ 31). When even asked if it might

be so rare that the case reports in all of medical science are in the single digits, he could not disagree. (PFOF, ¶ 25). Dr. Stec admitted he did not have any medical literature to support his opinion as to how fast a urethral polyp could develop. Additionally, Dr. Stec could not provide any literature to allow him to time the duration of time for the bladder changes to develop.

In light of this dearth of relevant knowledge or experience, Dr. Stec's causation opinions are speculative, lack the necessary medical scientific basis to be admissible, and must be excluded.

C. The opinions of Dr. Harris do not meet the *Daubert* reliability requirement.

Similar to Dr. Stec, the testimony of Dr. Harris establishes he does not have any direct or indirect experience with urethral polyps developing in a pediatric patient, and cannot provide any peer-reviewed medical literature or studies to support his opinion that a urethral polyp was a cause of mild hydronephrosis in 2014, or a urethral polyp were present and detectable during Dr. Henry's care of D.Y. Dr. Harris testified it was nearly certain that persistent or worsening hydronephrosis would have been present during the period of time Dr. Henry was seeing D.Y. (PFOF, ¶ 37). Dr. Harris stated the basis for his opinion was that when the diagnosis was finally made when D. Y. was four years of age, there was significant evidence of chronic long-standing high pressure in D.Y.'s bladder. *Id.* However, Dr. Harris admitted no medical literature or study existed to his knowledge to indicate *how long it takes*

for an obstruction to cause the type of changes seen in D.Y.'s bladder at age four. (PFOF, ¶¶ 38 and 39).

Of significance, he has also never treated a patient that had a urethral polyp, (PFOF, ¶ 40), and, like Dr. Stec, had never heard of a pediatric patient with a urethral polyp prior to this case. (PFOF, ¶ 41). Dr. Harris admitted not knowing how rare urethral polyps are, but ultimately admitted it appears to be an extremely rare event. (PFOF, ¶ 42). Dr. Harris only knew how rare it is to have pediatric patient with a urethral polyp *through this case*, and deferred to Dr. Stec's opinion. *Id.* Dr. Harris is not aware of any case studies or case reports of pediatric patients with urethral polyps. (PFOF, ¶ 43). More importantly, Dr. Harris admitted he does not have a basis for opining how fast a urethral polyp of this type grows or how long it needs to be present to cause the anatomic changes seen in D.Y.'s case. (PFOF, ¶ 44). Dr. Harris conceded 95% of mild hydronephrosis cases that are diagnosed antenatally resolve on their own without treatment. (PFOF, ¶ 45).

Dr. Harris admittedly assumed it would have taken *years* for the changes seen in D.Y.'s bladder in 2018 to have developed, but conceded he could cite to no literature on whether it takes months or years for those changes to develop depending on the nature of the obstruction or how rapidly urethral polyps can develop to cause an obstruction. Again, in light of this dearth of knowledge or experience, and supported by the case law cited above in support of excluding Dr. Stec's opinion, Dr. Harris's causation opinions are speculative, lack the necessary medical scientific basis to be admissible, and must be excluded.

CONCLUSION

Absent any admissible testimony as to causation, the plaintiff's claims and causes of action must be dismissed. The plaintiffs have not established Dr. Stec and Dr. Harris have relied on sufficient facts or data in reaching their causation opinion, and therefore their testimony must be excluded. Based on the above arguments, defendant Cynthia J. Henry, D.O. respectfully requests the Court grant her motion to strike plaintiffs' experts Dr. Stec and Dr. Harris pursuant to *Daubert* and, given the plaintiffs' failure to establish causation, grant summary judgment, dismissing the claims and causes of action against Dr. Henry with prejudice.

Dated at Milwaukee, Wisconsin this 17th day of October, 2024.

GUTGLASS, ERICKSON, LARSON & SCHNEIDER, S.C.

<u>electronically signed by Bradley S. Foley</u>
Mark E. Larson (State Bar No. 1016423)
Bradley S. Foley (State Bar No. 1026871)
Attorneys for Defendant Cynthia J. Henry, D.O.

P.O. ADDRESS:

735 N. Water St., Ste. 1400 Milwaukee, WI 53202-4267 (414)273-1144 mark.larson@gebsc.com bradley.foley@gebsc.com